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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,538	05/24/2001	Roger Y. Tsien	REGEN1530-2	4548

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EXAMINER

KAM, CHIH MIN

ARTICLE PAPER NUMBER

1653

DATE MAILED: 09/30/2002

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Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,538

Applicant(s)

TSIEN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claim 10 is an improper dependent claim because the claim cannot depend from itself.

To advance prosecution, claim 10 is read as being dependent from claim 9.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-26 and 43-53, drawn to a non-oligomerizing tandem fluorescent protein, comprising a first monomer of a fluorescent protein operatively linked to at least a second monomer of the fluorescent protein; a fusion protein comprising the non-oligomerizing tandem fluorescent protein operatively linked to at least one polypeptide of interest; a tandem non-oligomerizing fluorescent protein comprising a donor of a first fluorescent protein, an acceptor of a second fluorescent protein, and a peptide linker operatively linking the donor and the acceptor; a kit comprising at least one non-oligomerizing tandem fluorescent protein, classified in class 530, subclass 350, and class 435, subclass 69.7.

Should Invention I be elected, applicant is required to select one type of fluorescent protein from claim 2, and a specific fluorescent protein identified by a "SEQ ID NO:" from claim 4, 5, 8 or 9. Applicant is also required to select one type of polypeptide of interest from claim 22. Each fluorescent protein containing a different amino acid sequence has different chemical property and produces different effect, thus, is a distinct peptide. Each type of polypeptide of interest has different function and utility, thus is patentably distinct. This is not species election.

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II. Claims 27-42, drawn to a polynucleotide encoding a non-oligomerizing tandem fluorescent protein; a vector comprising the polynucleotide; a host cell containing the polynucleotide; and a kit comprising at least one recombinant nucleic acid molecule, classified in class 536, subclass 23.1, and class 435, subclasses 320.1 and 325.

III. Claims 54-65, drawn to a method of determining the pH of a sample comprising contacting the sample with the non-oligomerizing tandem fluorescent protein, wherein the emission intensity of the first non-oligomerizing tandem fluorescent protein changes as the pH varies between pH 5 to 10, classified in class 530, subclass 350, and class 435, subclass 69.7.

IV. Claim 66, drawn to a method of determining whether a sample contains an enzyme using the non-oligomerizing tandem fluorescent protein, classified in class 530, subclass 350, and class 435, subclass 69.7.

V. Claim 67, drawn to a method of determining the activity of an enzyme in a cell comprising providing a cell that express a tandem non-oligomerizing tandem fluorescent protein, classified in class 536, subclass 23.1, and class 435, subclass 325.

VI. Claims 68-75, drawn to a method of identifying the presence of a molecule in a sample, comprising operatively linking a non-oligomerizing tandem fluorescent protein to the molecule, and detecting fluorescence due to the non-oligomerizing tandem fluorescent protein, classified in class 530, subclass 350, and class 435, subclass 69.7.

Should Invention VI be elected, applicant is required to select one type of molecule from claim 70 or 71. Each type of molecule has different function and utility, thus is patentably distinct. This is not species election.

VII. Claims 68 and 76, drawn to a method of identifying the presence of a molecule in a sample, comprising operatively linking a non-oligomerizing tandem fluorescent protein to the molecule, and detecting fluorescence due to the non-oligomerizing tandem fluorescent protein, wherein the operatively linking comprises expressing a recombinant nucleic acid molecule comprising a polynucleotide encoding non-oligomerizing tandem fluorescent protein operatively linked to a polynucleotide encoding the molecule, classified in class 536, subclass 23.1, and class 435, subclass 325.

VIII. Claims 77-81, drawn to a method of identifying an agent or condition that regulates the activity of an expression control sequence, comprising exposing a recombinant nucleic acid molecule comprising a polynucleotide encoding a non-oligomerizing tandem fluorescent protein operatively linked to an expression control sequence to an agent or condition, and detecting fluorescence of the non-oligomerizing tandem fluorescent protein due to exposing, classified in class 536, subclass 23.1, and class 435, subclass 325.

IX. Claims 82-87, drawn to a method of identifying a specific interaction of a first molecule and a second molecule, comprising contacting the first molecule, which is operatively linked to a donor first non-oligomerizing tandem fluorescent protein, and the second molecule, which is operatively linked to an acceptor non-oligomerizing fluorescent protein under conditions that allow a specific interaction of the first molecule to the second molecule, and detecting fluorescence resonance energy from the donor to the acceptor, classified in class 530, subclass 350, and class 435, subclass 69.7.

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Should Invention IX be elected, applicant is required to select one type of molecules from claim 84 or 86. Each type of molecule has different function and utility, thus is patentably distinct. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Invention II are related to the polypeptides of Invention I because the polynucleotides encode the claimed peptides. The inventions are distinct because they are physically and functionally distinct chemical entities, and the peptide products can be made by another and materially different process, such as synthetic peptide synthesis or purification from natural source. Further, the polynucleotides may be used for process other than the production of the peptides, such as nucleotide hybridization assay.

The product of Invention I and the methods of Inventions III, IV, VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions III, IV, VI and IX are alternative processes of use of the product of Invention I.

The product of Invention I is distinct from the methods of Inventions V, VII and VIII because the product of Invention I can be neither made by nor used in the methods of V, VII and VIII.

The product of Invention II and the methods of Inventions V, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

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another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions V, VII and VIII are alternative processes of use of the product of Invention II.

The product of Invention II is distinct from the methods of Inventions III, IV, VI and IX because the product of Invention I can be neither made by nor used in the methods of III, IV, VI and IX.

The methods of Inventions III-IX are patentably distinct each from the other because they have different method steps, utilize different materials and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because Inventions I-IX require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

September 27, 2002

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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